

Appl. No. 10/810,358  
Docket No. 9188R&  
Amdt. Dated February 22, 2007  
Reply to Office Action mailed August 23, 2007  
Customer No. 27752

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### REMARKS

#### Claim Status

Claims 1-45 are pending in the present Application. Claims 7, 8, 13, 14, and 24-45 have been withdrawn from consideration. Claims 1-6, 9-12 and 16-23 are rejected. Claims 22-23 were evaluated under 35 USC § 112, 6<sup>th</sup> paragraph (means plus function). Claims 1-17, 19, 20, and 22 have been amended primarily to clarify the claim language. No new matter has been added. Thus, entry and consideration of the amendments is respectfully requested.

### OBJECTIONS

#### IDS

The two previously-filed Information Disclosure Statements, filed 20 June 2004 and 30 June 2005 are not in compliance with 37 CFR § 1.97, 1.98 and MPEP § 609. A supplemental IDS is being submitted under separate cover, to provide the additionally required information for some of the previously-listed documents, as required by the Examiner. Therefore, all documents submitted for consideration have been fully cited, and the objection has been overcome. The Applicants therefore request that the objection be withdrawn.

#### Claim Objections

Claims 2-5 and 12 are objected to as encompassing non-elected inventions. As stated by the Examiner, Claims 1-6, 9-12, 16-23 are under consideration to the extent they read on the elected invention. The Applicants elected, for initial searching, interleukin-10 as the anti-inflammatory cytokine, interleukin-12 as the pro-inflammatory cytokine, and a probiotic as the compound inducing *in vitro* stimulation. Claims 2 and 3 recite interleukin-10, the elected anti-inflammatory cytokine. Claims 4 and 5 recite interleukin-12, the elected pro-inflammatory cytokine. Claim 12 recites a probiotic, the elected compound inducing *in vitro* stimulation. Therefore, Claim 2-5 and 12 encompass elected inventions and should be considered to the extent they read on the elected species. Thus, Claims 2-5 and 12 are not amended or withdrawn at this time, with respect to the elected species, and the Applicants respectfully request that the Objection be withdrawn.

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### REJECTIONS

#### Rejection Under 35 USC § 112, 2<sup>nd</sup> Paragraph

Claims 1-23 are rejected under 35 USC § 112, 2<sup>nd</sup> Paragraph as being indefinite.

#### Claim 1

The Examiner asserts that Claim 1 is an incomplete method claim. Claim 1 has been amended to clarify the method of Claim 1 relating to efficacy of treatment. Therefore, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

#### Claims 2 and 3

Claims 2 and 3 are rejected as reciting improper Markush Groups. Claims 2 and 3 have been amended to put the Markush groups in proper form. Therefore, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

#### Claims 1, 6, 22, 2, 3, 16-18, 4, 5, and 19-21

Claims 1, 6 and 22 recite "anti-inflammatory cytokine" and "pro-inflammatory cytokine". Claims 2, 3, and 16-18 recite "anti-inflammatory cytokine", and Claims 4, 5, and 19-21 recite "pro-inflammatory cytokine". The Examiner asserts essentially that cytokines can be anti-inflammatory or pro-inflammatory based on the context in which they are found because cytokines have multiple target cells and multiple actions. Thus, the Examiner asserts that these Claims are vague and indefinite.

The Applicants respectfully traverse the rejection. Claims 2 and 3 define the intended "anti-inflammatory cytokines" as used in the context and methods of the invention. Claims 4 and 5 define the intended "pro-inflammatory cytokines" as used in the context and methods of the invention. Thus, the Claims are not vague and indefinite as to what is meant by the phrases "anti-inflammatory cytokines" and "pro-inflammatory cytokines" with respect to inflammatory diseases of the bowel in mammals. The Applicants acknowledge, in the Specification at the last sentence of page 2 through the second full paragraph on page 3, that cytokine action is contextual and that cytokines can express multiple biologically overlapping activities. Therefore, the Applicants have defined which particular cytokines are considered "anti-inflammatory" and which are

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considered "pro-inflammatory" in the context and methods of the present invention with respect to inflammatory diseases of the bowel. Therefore, the Applicants have particularly pointed out and distinctly claimed the subject matter they regard as the invention, and the rejection has been overcome. The Applicants respectfully request that the rejection be withdrawn.

#### Claims 2-5

Claims 2-5 are deemed vague and indefinite for reciting specific cytokines and "mixtures thereof", as the Examiner does not understand what the Applicants intend to measure.

The Applicants respectfully traverse the rejection. Claims 2-5 are in Markush format. Claiming in Markush format is a well understood and accepted claim format. If desired, one could measure levels and ratios of more than one pair of cytokines. Thus, indicating "and mixtures thereof" in the Claims is not vague or indefinite. One of skill in the art would understand that levels of one, two or more cytokines could be measured, or levels of all of the recited anti-inflammatory and pro-inflammatory cytokines could be measured and ratios of the levels compared.

Beginning at page 11 of the Specification, the Applicants clearly describe that levels of *at least one* anti-inflammatory cytokine can be measured and the level compared to the level of *at least one* pro-inflammatory cytokine. The preferred cytokines from which to choose are described, as recited in Claims 2-5. It is also described that levels of any anti-inflammatory cytokine, as described in the Specification, can be compared to levels of any pro-inflammatory cytokine as described in the Specification. See page 12, lines 31-33 wherein particularly useful ratios of particular cytokines are described. Thus, ratios of particular cytokines are believed to be particularly indicative of efficacy of treatment for inflammatory bowel diseases, however, levels of any of the recited cytokines can be measured.

Thus, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

#### Claim 6

Claim 6 is deemed vague and indefinite because the recitation "wherein said ratio of anti-inflammatory cytokine to pro-inflammatory cytokine is interleukin-10/interleukin-12" does not contain mathematical expressions. The Examiner suggests amending the

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claims to recite "wherein said anti-inflammatory cytokine is interleukin-10 and said pro-inflammatory cytokine is interleukin-12.

The Applicants respectfully traverse the rejection. Claim 6 has been amended to clarify the calculated ratio. Therefore, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

#### Claims 9-11

Claims 9-11 are deemed vague and indefinite for reciting "peripheral blood mononuclear cells with *in vitro* stimulation" because the Examiner is not clear as to when the stimulation occurs, what cytokine levels are measured, and whether all the recited elements are to be used together or separately.

The Applicants respectfully traverse the rejection. Claims 9-11, as amended, are Markush groups, written in an alternative acceptable format. Claiming in Markush format is a well understood and accepted claim format. Thus, it is clear that a biological sample can be obtained from any of the recited types of samples, that more than one of the sample types may be taken and tested, and that different combinations of samples can be obtained and tested.

In addition, as defined at page 8, lines 15-19 "*in vitro* stimulation" includes stimulation of the biological sample outside of the donor's body, i.e. after sample collection.

Therefore, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

#### Claim 12

Claim 12 is deemed vague and indefinite for reciting "wherein said *in vitro* stimulation comprises a mitogen, probiotic, anti-CD3 molecule and mixtures thereof", because those components may provide a means for stimulation but can not comprise stimulation. Also, the Examiner is unclear as to what the recited mixtures comprise or whether the recited elements are to be used together or separately.

The Applicants respectfully traverse the rejection. Claim 12 has been amended to clarify that the stimulation is with one of the recited components. Furthermore, Claim 12, as amended, is a Markush group written in an alternative format. Markush style claiming

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is a well understood and accepted claim format. Thus, one would understand that the stimulation could occur with one or more of the members of the recited group, individually or in combination.

Therefore, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

#### Claims 16-21

Claims 16-21 recite the limitation "the method according to claim...wherein...", and the Examiner asserts that there is insufficient antecedent basis for this limitation.

The Applicants respectfully traverse the rejection. The Claims have been amended, and provide antecedent basis for all elements. Therefore, the Applicants respectfully request that the rejection be withdrawn.

#### Claims 16, 17, 19, and 20

Claims 16, 17, 19, and 20 are deemed vague and indefinite for reciting assay methods and mixtures thereof. Also, Claims 16 and 19 recite means of measuring cytokines and include methods that the Examiner asserts measure nucleic acids, not proteins, and would not be able to measure cytokine levels.

The Applicants respectfully traverse the rejections. Claims 16, 17, 19 and 20 have been amended. The Claims recite that mRNA and/or protein expression can be measured. Therefore, the nucleic acid measuring techniques are appropriately included within the Claims. See the Specification at page 11, last paragraph.

In addition, these Claims are written as a Markush group in an alternative format. Markush style claiming is a well understood and accepted claim format. Thus, one would understand that the means for measuring could be any of the members of the group, used, individually or in combination – i.e. one could measure levels of cytokine using one or more than one method.

Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

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#### Claim 22

The Examiner asserts that Claim 22 appears to intend to invoke 35 USC § 112 sixth paragraph, but asserts that in order to invoke 35 USC § 112 sixth paragraph the claim *must* be amended to recite the phrase "means for".

The Applicants respectfully traverse the rejection. In order to invoke 35 USC § 112 sixth paragraph, it is not necessarily required that one *must* use the phrase "means for". See MPEP § 2181. However, the Applicants do not necessarily intend to invoke 35 USC § 112 sixth paragraph.

The Examiner also asserts that Claim 22 is vague and indefinite because the recited "measuring element or system" does not include structural limitations. Thus, the Examiner asserts that it is unclear how an element or system could be used to measure levels of protein. A system does not necessarily have to contain structural limitations. Therefore, structural limitations are not required. In addition, an applicant can be his own lexicographer. In the present case, page 13, beginning at line 11, kits of the present invention are described and the types of measurement elements and systems usable with the methods of the invention are described. Thus, the elements and systems included in the kit of Claim 22 are defined and therefore are not vague and indefinite because it is clear from the specification how such elements and/or systems can be used to measure cytokine levels.

Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

#### Claims 18 and 23

Claims 18 and 23 are included in the rejections as being dependent on rejected base claims.

The Claims upon which Claims 18 and 23 depend are allowable, and thus Claims 18 and 23 are also allowable. Therefore, the Applicants respectfully request that the rejection be withdrawn.

#### Rejection Under 35 USC § 112, 1<sup>st</sup> Paragraph

Claims 1-23 are rejected under 35 USC § 112, 1<sup>st</sup> Paragraph failing to comply with the enablement requirement.

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Claims 1-21 are rejected because the Examiner asserts that the specification, while being enabling for a method of determining the efficacy of a treatment of inflammatory diseases of the bowel in mammals *in vitro*, is *not* enabling for methods of determining the efficacy of a treatment of inflammatory diseases of the bowel in mammals *in vivo*.

The Examiner asserts that Claim 1 is broadly drawn to a method of determining efficacy of *any* treatment of inflammatory diseases of the bowel *in vivo* in mammals, but that the Claim is not enabled for the broad scope recited. The Examiner asserts that the Specification and working examples only disclose *one* method and compound for treatment of inflammatory bowel disease – that of feeding a probiotic preparation containing *Bifidobacterium infantis*. The Examiner asserts that because the etiologies of inflammatory bowel disease are complex and remain poorly understood, the administration of such compounds would not indicate efficacy of a particular treatment and that one of ordinary skill would not be able to predict whether one could evaluate the efficacy of *any* treatment by measuring cytokine ratios.

Additionally, the Examiner asserts that because some cytokines are known to be pleiotropic and express biologically overlapping activities, and that some cytokines have pro and anti-inflammatory functions, it would require undue experimentation to determine which cytokines have pro or anti-inflammatory effects in the context of the system of the present invention, and then determine ratios indicative of efficacy of treatment.

The Examiner asserts that the Specification only discloses one example method of determining efficacy of treatment, which method includes a combination of and *in vivo* treatment method and an *in vitro* method of evaluating the efficacy of the treatment. Thus, the Examiner asserts that one would not be able to predict what changes in cytokine levels from what samples would be indicative of treatment.

The Examiner also asserts that the Specification does not teach a nexus between changes in the ratio of anti-inflammatory to pro-inflammatory cytokine levels and any objective indication of inhibition of inflammatory bowel disease, but only teaches a correlation between cytokine ratios and change in abdominal pain. The Examiner asserts that one of skill in the art would recognize that perceived relief of symptoms is not necessarily indicative of inhibition of actual disease progression, thus, one of skill would not be able to predict that changes in ratios of cytokine levels would be correlative to any objective indications of inhibition of inflammatory bowel disease. Thus, the Examiner asserts that undue experimentation would be required to determine which potential

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treatments would result in alterations of cytokine ratios, and levels of which cytokines might be indicative of efficacy of treatment, because of the absence of other than the one working example, the complex nature of the invention, the knowledge that cytokines can have anti and pro-inflammatory effects, and the breadth of the Claims.

The Applicants respectfully traverse the rejections. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. See MPEP § 2164.01 citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ 2d 1217, 1223 Fed. Cir. 1988. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. See MPEP § 2164.01 citing *In re Certain Limited-Charge Cell Culture Microcarriers* 221 USPQ 1165, 1174, Int'l Trade Comm'n 1983, *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.V. Fortia*, 774 F.2d 1104, 227 USPQ 428 Fed. Cir. 1985.

The factors to be considered to determine whether experimentation is "undue" include the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a).

The Examiner asserts that the claim breadth is too broad; the nature of inflammatory bowel disease is complex; the Specification and examples only disclose one working example; that it would require undue experimentation to determine which cytokines have pro or anti-inflammatory effects in the context of the system of the present invention, and then determine ratios indicative of efficacy of treatment; that the Specification does not teach a nexus between changes in the ratio of anti-inflammatory to pro-inflammatory cytokine levels and any objective indication of inhibition of inflammatory bowel disease; that because some cytokines are known to be pleiotropic and express biologically overlapping activities, and that some cytokines have pro and anti-inflammatory functions, it would require undue experimentation to determine which cytokines have pro or anti-inflammatory effects in the context of the system of the present invention, and then determine ratios indicative of efficacy of treatment.

The Applicants assert that undue experimentation would not be required by one of skill in the art in order to practice the invention, and that the Claims are enabled. The

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Applicants provide sufficient background for one of skill in the art to understand the problems associated with inflammatory bowel diseases, and the methods and technologies described in the present Specification. In addition, the level of skill of one in the art would be relatively high as the invention involves scientific and medical principles. Furthermore, complex experimentation is common to the biological and medicinal arts.

The Applicants also assert that nexus between changes in ratios of cytokines and efficacy treatment for inflammatory bowel diseases has been made. See page 2, lines 32-35 through page 3, line 14, and page 7, lines 12-20 of the Specification. As the Examiner points out, at pages 10 and 11 of the Official Action, one could predict that treatment of inflammatory bowel diseases by a wide variety of treatments might alter the ratio of anti-inflammatory cytokines to pro-inflammatory cytokines. However, the Examiner confusingly then states that the alterations in cytokine ratios would be due to administration of the drugs, and would not indicate efficacy of treatment. If, as described in the Specification, cytokine ratios, rather than levels of any one cytokine, are indicative of normal vs. disease bowel conditions, then changes in such ratios vs. normal ratios would be indicative of bowel disease and also efficacy of treatment including compounds administered for treatment of bowel disease. Thus, one could connect the changes in cytokine ratios to efficacy of treatment.

Furthermore, the presence of only one working example is just one of the factors to be considered with respect to enablement, but number of working examples alone is not determinative of enablement. See MPEP § 2164.02. Although only one working example is provided, the guidance, and definitions provided in the Specification would certainly allow one of skill in the art to be able to determine, without undue experimentation, which types of cytokines can be measured and compared, and how to do such measurement and comparison.

Therefore, the Applicants assert that based on the description and definitions provided in the Specification, including example anti-inflammatory cytokines, pro-inflammatory cytokines, types of samples that can be tested, types of stimulating agents that can be used *in vitro* and *in vivo*, and the presence of a working example, one of skill in the art would be able to understand and make or use the invention. Thus, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

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Claims 22 and 23

Claims 22 and 23 are rejected under 35 USC § 112, 1<sup>st</sup> Paragraph, because the Examiner asserts that the Specification is enabling for a kit using IL-10, peripheral blood mononuclear cells with *in vitro* stimulation, wherein the ratio of IL-10 to IL-12, TNF- $\alpha$  or IFN- $\gamma$  is indicative of *efficacy* of treatment, but is *not* enabling for a kit using *any* anti-inflammatory cytokine, in *any* biological sample, measuring *any* pro-inflammatory cytokine, in *any* sample, being indicative of *an inhibitor* of inflammatory disease of the bowel. The Examiner's reasons are essentially the same as above, including assertion of undue experimentation, one working example, complex nature of the invention, that some cytokines can be anti and/or pro-inflammatory, and the breadth of the Claims.

The Applicants respectfully traverse the rejection. While the Examiner has laid out the factors to consider in making enablement determinations, based on MPEP § 2164.01(a), the Applicants assert that the Claims are enabled. While limitations from the specification are not to be read into claims, the claims are interpreted in light of the specification.

The anti-inflammatory cytokines of the present invention are defined in the Specification, and thus should not be limited to only IL-10 just because the working example happens to measure IL-10. The presence of only one working example is just one of the factors to be considered with respect to enablement. See MPEP § 2164.02.

Similarly, the biological samples usable with the methods of the present invention are defined in the Specification, and thus should not be limited to only peripheral blood mononuclear cells with *in vitro* stimulation. One of skill in the art would understand what sample types are usable and how to obtain such samples. Undue experimentation would not be required.

Similarly, the pro-inflammatory cytokines of the present invention are defined in the specification, and thus should not be limited to only IL-12, TNF- $\alpha$  or IFN- $\gamma$ .

Thus, the anti-inflammatory cytokines, the biological sample, and the pro-inflammatory cytokines of the kits of the present invention are those described and defined in the Specification, and should not be limited to only those described in the working example, even if there is only one working example.

Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

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Rejections Under 35 USC § 102

Claim 22 is rejected under 35 USC § 102(b) as being anticipated by Vignali, 2000 Journal of Immunological Methods 243:243-255 (hereafter "Vignali"). The Examiner asserts that there are no structural limitations in the Claim, and that Vignali discloses a structural use of an assay methodology to measure cytokine levels in an animal model for toxic shock syndrome. Therefore, the Examiner asserts that Vignali anticipates all of the limitations of Claim 22.

The Applicants respectfully traverse the rejection. Under 35 USC §102, anticipation requires that all the Claim elements appear in a single prior art document. "A Claim is anticipated only if each and every element set forth in the Claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 citing *Verdegel Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the ... Claim." MEPE § 2131 citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2D 1913, 1920 (Fed. Cir. 1989).

Vignali discloses that the simultaneous detection of various analytes can be achieved using the FlowMetrix™ assay. Vignali discloses that multiple cytokine levels can be measured simultaneously. However, Vignali discloses nothing with respect to ratios of analytes in general or cytokines in particular. Claim 22 recites that a ratio of cytokine levels is determined and examines changes in the cytokine ratio. There is nothing in Vignali that discloses anything with respect to using ratios of analytes to indicate anything.

Furthermore, Claim 22 recites a kit. Vignali does not disclose a kit. Vignali simply uses an assay method to measure various analytes and discusses the advantages and disadvantages of various assay methods and devices. No kit is ever described in Vignali. In addition, Claim 22 recites providing instructions to a user. Vignali does not disclose providing instructions to users of a kit.

Therefore, all elements of the Claim are not found in Vignali and thus Vignali can not, as a matter of law, anticipate the Claim. The Applicants, therefore, respectfully request that the rejection be withdrawn.

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35 USC § 103

Claim 23 is rejected under 35 USC § 103(a) as being unpatentable over Vignali. The Examiner asserts that Vignali discloses a kit for measuring cytokines in a biological sample from a mammalian subject. The Examiner acknowledges that Vignali does not disclose a kit comprising means for collecting biological samples. However, the Examiner asserts that it would have been obvious for one of ordinary skill in the art to include a device for obtaining a sample, that one would be motivated because it would increase the efficiency of the kit of Vignali to include sampling devices, and that one would reasonably have expected success because "kits by various manufacturers contain a wide variety of materials".

The Applicants respectfully traverse the rejection. The Examiner has not established a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

The Examiner asserts that Vignali discloses a kit for measuring cytokines in a biological sample. Nowhere does Vignali disclose a kit. Vignali only discloses various assay methods and devices, and compares them. Thus, there is no teaching, suggestion or motivation to provide any sort of kit, regardless of its components. Thus, because there is no teaching or suggestion to provide a kit at all, there is no motivation to add to such a kit a means for collecting biological samples. Even if, as stated by the Examiner, "kits by various manufacturers contain a wide variety of materials" such information would not have led one of skill in the art to the present invention. Vignali simply performs various assays on various equipment to test the limits, practicality, cost, advantages and disadvantages of various assays done on various equipment. There is nothing in Vignali that teaches or suggests any kit, regardless of its components. Thus, there is no expectation of success found in Vignali for adding to a kit a means for collecting biological samples.

Furthermore, Claim 22, from which Claim 23 depends, recites determining ratios and including instructions to users of the kit. Vignali does not teach, suggest or provide any motivation or expectation of success for determining ratios of analytes to indicate

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anything. Nor does Vignali teach, suggest or provide any motivation for including any instructions in a kit. Thus, Vignali does not disclose every element of the Claim because Vignali does not disclose a kit, does not disclose determining ratios of analytes, and does not disclose instructions to a user.

Therefore, Vignali does not provide the requisite suggestion, motivation, expectation of success to have led one of ordinary skill in the art to the present invention, and does not disclose every element of the present invention. Thus, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

Conclusion

The Applicants therefore respectfully request that Examiner reconsider the Application. Early allowance of all pending Claims is respectfully requested. If the Examiner believes that personal contact would be beneficial for disposition of the present application, the Examiner is respectfully requested to contact the undersigned.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By   
Signature

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